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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,660	03/19/2001	Roman Efrain Vasquez Lipi	2119-109	9057

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/810,660	<b>Applicant(s)</b> VASQUEZ LIPI, ROMAN EFRAIN	
	<b>Examiner</b> Gina C. Yu	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,17 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15,17 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 5, 2005 has been entered.

## **REQUEST FOR INFORMATION**

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

Applicant is asked to submit documents showing (a) the formulas (including the amounts of the ingredients) of Sencil Pediatric, Hemorrhoids, Dermal, Vaginal products; and (b) the date on which these Sencil products were made available for public use or sale in the United States.

Applicant has disclosed in declaration and remarks d December 5, 2005, that Sencil ointment is representative of applicants' invention. A further search by examiner have revealed that Sencil has been commercially available over 20 years and sold in the United States as an over-the-counter medication for proctologic, pediatric, and dermatological applications for minor burns, cuts, and abrasions. See CAC Pharmaceuticals, Market Tested. 35 U.S.C. § 102 (b) requires that no patent is allowed

if the invention was in public use or on sale in this country, more than one year prior to the date of application for patent in the United States. Thus, examiner finds it necessary to review the facts relating to the public use and sales activity of the product that applicant has disclosed as representative of the present invention.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 2, 5-15, 17, 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over George (US 3431340) in view of Soto (Derwent Acc. No. 1984-271531), Arhens (US 3825563), Kaplan (US 5047232), and Slimak (US 6099866).**

George teaches that castor oil and cod liver oil are well known for the treatment of burns. See col. 2, lines 1 – 61. The reference teaches a topical composition consisting essentially of 35-65 % by weight of castor oil and 35-65 % by weight of cod liver oil. The reference recites, “[t]he castor oil prevents the growth of scar tissue, and the fish oil controls the caustic action of the castor oil, while at the same time promoting the healing of the wounds.” See col. 2, lines 45 – 48; see also col. 2, lines 15 – 26.

The reference also teaches that cod liver oil contains at least 1000 USP units of vitamin A and 100 USP units of vitamin D per gram. See col. 2, lines 21 – 26. The reference further teaches that “[a]dditional quantities of vehicles, vitamins, and other fortifying substances may be as required.” See col. 2, lines 9-14. See instant claims 6-8, 10-13.

George fails to teach the remaining components recited in claim 1.

Soto teaches method of treating skin injuries by topically applying a composition comprising essentially of olive oil (100 parts) and beeswax (10 parts) as the principal ingredients. See abstract. The reference also teaches that one of more aromatic plant oils can be further incorporated therein.

Ahrens teaches a vitamin E (d-alpha-tocopheryl-acid-succinate) cream compositions having sweet almond oil and mineral oil (petrolatum) base. The reference teaches that the compositions provide stable and economic means to provide the therapeutic effects of vitamin E. See the amounts of the ingredients in Tables 1, 2, and 3. See instant claim 17. The reference specifically teaches that the application of Vitamin E to burn skin "immediately" relieved pain, renewed the skin layers afterwards and provided healing effects on the third day. See col. 8, lines 7 – 21. See instant claims 9, 14, and 15.

Kaplan teaches that almond oil and castor oil are emollients well known to one having ordinary skill in the art. See col. 3, lines 66-67; col. 4, lines 34 – 3. Specific examples that these oils are used in mineral oil-based composition are shown in Examples 1, 2, 3, and 13. See instant claim 17. The examples also employ vitamin E in the weight amount of 0.1 -1 % by weight. See instant claim 9.

Slimak teaches a composition comprising beeswax and oil, with or without water, useful for treating topical wounds including burns. See abstract. The reference specifically provides motivation to limit the ingredients to wax, oil, and water, due to possibility of allergic reactions. See col. 12, lines 37 – 43. The reference teaches that antibiotics may be added. See col. 13, lines 10 – 17. See instant claim 22. Slimak

teaches to combine the beeswax with plant oils and suggest that animal oil can be further added therein. See col. 12, lines 16 – 44. Almond, olive, sunflower, and mineral oils are disclosed. It is well known in the art that sunflower oil also contains vitamin E. The reference further teaches that “an oil similar to the plant source of the wax” is preferably used, which include sunflower and olive oils. Accordingly, a skilled artisan would have been motivated to select these oils to combine with the beeswax composition. The Slimak reference teaches when water, the excipient in this case, is used, the volume ratio of wax:oil:water can range from 1:0.1:0 to 1:6:6 to produce a soft, easily applicable composition for topical application to the skin. See col. 10, lines 55 – 60. See instant claim 2.

While the specific weight amount of the each of oil components are not taught as recited in the instant claim, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in the combined references, examiner views that one having ordinary skill in the art would have discovered the optimum or workable weight amount of the ingredients by routine experimentation. The skilled artisan would have considered the cost of the ingredients or the rheology or spreadability of the final product, as suggested by Slimak. See col. 10, lines 55 – 60. See also In re Boesch, 205 U.S.P.Q. 215 (C.C.P.A. 198) (holding it is within the skill in the art to select optimal parameters, such as amount)

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teachings in the George, Soto, Ahren, and Kaplan. As shown by the references, the instant claims define the concomitant use of conventional therapeutic agents known for burn treatment. It would follow that the combination of beeswax, olive oil, castor oil, and cod liver oil and the method of use thereof is prima facie obvious.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the George composition by adding the additional ingredients of the secondary references because

- 1) all references are directed to burn skin treatment compositions;
- 2) George specifically teaches to further incorporate "vehicles, vitamins, and other fortifying substances" to the castor oil/cod liver oil composition;
- 3) the skilled artisan would have had expectation that addition of olive oil and beeswax have additive effect in burn skin treatment composition, as taught by Soto;
- 4) the skilled artisan would have expected that further addition of petrolatum and almond oil to mix with vitamin E composition produces a stable therapeutic composition with enhanced healing effect on burn skin, as taught by Ahren;
- 5) the skilled artisan would have also expected that using natural oil such as sunflower oil for beeswax and further adding preservative would successfully produce a

further stable burn treatment composition with an enhanced effectiveness, as taught by Slimak.

**Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over George, Soto, Arhens, and Slimak as applied to claims 1, 2, 5-15, 17, 24-27 above, and further in view of Martin (US 5874479).**

The combined references fail to teach butylhydroxytoluene (BHT).

Martin teaches topical wound-healing compositions useful for, among others, healing of burns. See col. 23, lines 1 –9. The reference teaches that BHT is an art-recognized preservative. See col. 13, lines 53-54. See instant claim 23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding BHT in the composition because Martin teaches that BHT is a conventional preservative well known in pharmaceutical art. The skilled artisan would have had a reasonable expectation of successfully producing a skin treatment composition with longer shelf-life because Slimak teaches to add a preservative and the compositions of the combined references and Martin are topical formulations.

#### ***Oath/Declaration***

Declaration filed on December 5, 2005 has been fully considered. Examiner views that the declaration does not place the application in condition for allowance because the data provided therein is not commensurate with the scope of the claims. Declarant states that Sencil is a mixture of olive oil, almond oil, castor oil, sunflower oil, and beeswax, and provides a superior skin treatment effects as compared to Ointment



B, which contains only olive oil and beeswax in approximately equal proportions. It should be noted that the prior arts suggest that addition of almond oil, castor oil, sunflower oil would provide enhanced skin treatment effects. While Claim 1 recites specific weight limitation of each of the active ingredients, it cannot be verified whether Sencil formulation used in the comparison also contains the active ingredients in the amount as claimed by applicants. Thus, examiner views that the declaration does not provide any evidence to support that the recited weight amount of the active ingredients is critical to the present invention.

#### ***Response to Arguments***

Applicant's arguments filed on December 5, 2005 have been fully considered but they are not persuasive.

Applicant asserts that a skilled artisan, even in view of the combined teachings of the cited references could not have predicted anything about the clinical results obtained by the declarant and the non-greasy feeling of the claimed mixture. In response, examiner reiterates that each the dermatological function of each active oils is found in the cited references: castor oil and cod liver oil provide skin wound-healing effects and contains Vitamins; sweet almond oils provide pain-relief and emolliency; and bees wax and sunflower oil heal skin injury. Adjusting the weight amount of the active ingredients to obtain an optimum formulation would have been within the skill of the art, unless there is evidence indicating that such concentration is critical.

#### ***Conclusion***


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 9:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner

  
**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**